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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/848,948 | 05/04/2001 | Samir M. Hanash | A31909-PCT USA | 8499 |

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| EXAMINER | |
|---|---|
| RAWLINGS, STEPHEN L | |
| ART UNIT | PAPER NUMBER |
| 1642 | |

DATE MAILED: 09/17/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Acti n Summary | Application No. 09/848,948 | Applicant(s) HANASH ET AL. | |
|---|---|---|---|
| | Examiner Stephen L. Rawlings, Ph.D. | Art Unit 1642 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Peri d for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) 1-32 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-32 are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Pri rity under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *election facsimile cover sheet* .

## DETAILED ACTION

1. Claims 1-32 are pending in the application and are currently subject to restriction.

### *Election/Restrictions*

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 1-7 and 14-18, insofar as the claims are drawn to a method for diagnosis, wherein said method comprises detecting S100-AG, and a kit comprising a component for detecting said protein, classified in class 435, subclass 7.1 and, for example, in class 530, subclass 388.1.

Group II. Claims 1-7 and 14-18, insofar as the claims are drawn to a method for diagnosis, wherein said method comprises detecting S100-A7, and a kit comprising a component for detecting said protein, classified in class 435, subclass 7.1 and, for example, in class 530, subclass 388.1.

Group III. Claims 1-7 and 14-18, insofar as the claims are drawn to a method for diagnosis, wherein said method comprises detecting S100-A8, and a kit comprising a component for detecting said protein, classified in class 435, subclass 7.1 and, for example, in class 530, subclass 388.1.

Group IV. Claims 1-7 and 14-18, insofar as the claims are drawn to a method for diagnosis, wherein said method comprises detecting S100-A9, and a kit comprising a component for detecting said protein, classified in class 435, subclass 7.1 and, for example, in class 530, subclass 388.1.

Group V. Claims 1-7 and 14-18, insofar as the claims are drawn to a method for diagnosis, wherein said method comprises detecting S100-AG and S100-A7, and a kit comprising a component for detecting said proteins,

classified in class 435, subclass 7.1 and, for example, in class 530, subclass 388.1.

Group VI. Claims 1-7 and 14-18, insofar as the claims are drawn to a method for diagnosis, wherein said method comprises detecting S100-AG and S100-A8, and a kit comprising a component for detecting said proteins, classified in class 435, subclass 7.1 and, for example, in class 530, subclass 388.1.

Group VII. Claims 1-7 and 14-18, insofar as the claims are drawn to a method for diagnosis, wherein said method comprises detecting S100-AG and S100-A9, and a kit comprising a component for detecting said proteins, classified in class 435, subclass 7.1 and, for example, in class 530, subclass 388.1.

Group VIII. Claims 1-7 and 14-18, insofar as the claims are drawn to a method for diagnosis, wherein said method comprises detecting S100-A7 and S100-A8, and a kit comprising a component for detecting said proteins, classified in class 435, subclass 7.1 and, for example, in class 530, subclass 388.1.

Group IX. Claims 1-7 and 14-18, insofar as the claims are drawn to a method for diagnosis, wherein said method comprises detecting S100-A7 and S100-A9, and a kit comprising a component for detecting said proteins, classified in class 435, subclass 7.1 and, for example, in class 530, subclass 388.1.

Group X. Claims 1-7 and 14-18, insofar as the claims are drawn to a method for diagnosis, wherein said method comprises detecting S100-A8 and S100-A9, and a kit comprising a component for detecting said proteins,

classified in class 435, subclass 7.1 and, for example, in class 530, subclass 388.1.

Group XI. Claims 1-7 and 14-18, insofar as the claims are drawn to a method for diagnosis, wherein said method comprises detecting S100-AG, S100-A7, and S100-A8, and a kit comprising a component for detecting said proteins, classified in class 435, subclass 7.1 and, for example, in class 530, subclass 388.1.

Group XII. Claims 1-7 and 14-18, insofar as the claims are drawn to a method for diagnosis, wherein said method comprises detecting S100-AG, S100-A7 and S100-A9, and a kit comprising a component for detecting said proteins, classified in class 435, subclass 7.1 and, for example, in class 530, subclass 388.1.

Group XIII. Claims 1-7 and 14-18, insofar as the claims are drawn to a method for diagnosis, wherein said method comprises detecting S100-A7, S100-A8, and S100-A9, and a kit comprising a component for detecting said proteins, classified in class 435, subclass 7.1 and, for example, in class 530, subclass 388.1.

Group XIV. Claims 1-7 and 14-18, insofar as the claims are drawn to a method for diagnosis, wherein said method comprises detecting S100-AG, S100-A7, S100-A8, and S100-A9, and a kit comprising a component for detecting proteins, classified in class 435, subclass 7.1 and, for example, in class 530, subclass 388.1.

Group XV. Claims 1-7 and 14-18, insofar as the claims are drawn to a method for prognosis, wherein said method comprises detecting S100-AG, and a

kit comprising a component for detecting said protein, classified in class 435, subclass 7.1 and, for example, in class 530, subclass 388.1.

Group XVI. Claims 1-7 and 14-18, insofar as the claims are drawn to a method for prognosis, wherein said method comprises detecting S100-A7, and a kit comprising a component for detecting said protein, classified in class 435, subclass 7.1 and, for example, in class 530, subclass 388.1.

Group XVII. Claims 1-7 and 14-18, insofar as the claims are drawn to a method for prognosis, wherein said method comprises detecting S100-A8, and a kit comprising a component for detecting said protein, classified in class 435, subclass 7.1 and, for example, in class 530, subclass 388.1.

Group XVIII. Claims 1-7 and 14-18, insofar as the claims are drawn to a method for prognosis, wherein said method comprises detecting S100-A9, and a kit comprising a component for detecting said protein, classified in class 435, subclass 7.1 and, for example, in class 530, subclass 388.1.

Group XIX. Claims 1-7 and 14-18, insofar as the claims are drawn to a method for prognosis, wherein said method comprises detecting S100-AG and S100-A7, and a kit comprising a component for detecting said proteins, classified in class 435, subclass 7.1 and, for example, in class 530, subclass 388.1.

Group XX. Claims 1-7 and 14-18, insofar as the claims are drawn to a method for prognosis, wherein said method comprises detecting S100-AG and S100-A8, and a kit comprising a component for detecting said proteins, classified in class 435, subclass 7.1 and, for example, in class 530, subclass 388.1.

Group XXI. Claims 1-7, insofar as the claims are drawn to a method for prognosis, wherein said method comprises detecting S100-AG and S100-A9, and a kit comprising a component for detecting said proteins, classified in class 435, subclass 7.1 and, for example, in class 530, subclass 388.1.

Group XXII. Claims 1-7 and 14-18, insofar as the claims are drawn to a method for prognosis, wherein said method comprises detecting S100-A7 and S100-A8, and a kit comprising a component for detecting said proteins, classified in class 435, subclass 7.1 and, for example, in class 530, subclass 388.1.

Group XXIII. Claims 1-7 and 14-18, insofar as the claims are drawn to a method for prognosis, wherein said method comprises detecting S100-A7 and S100-A9, and a kit comprising a component for detecting said proteins, classified in class 435, subclass 7.1 and, for example, in class 530, subclass 388.1.

Group XXIV. Claims 1-7, insofar as the claims are drawn to a method for prognosis, wherein said method comprises detecting S100-A8 and S100-A9, and a kit comprising a component for detecting said proteins, classified in class 435, subclass 7.1 and, for example, in class 530, subclass 388.1.

Group XXV. Claims 1-7, insofar as the claims are drawn to a method for prognosis, wherein said method comprises detecting S100-AG, S100-A7, and S100-A8, and a kit comprising a component for detecting said proteins, classified in class 435, subclass 7.1 and, for example, in class 530, subclass 388.1.

Group XXVI. Claims 1-7, insofar as the claims are drawn to a method for prognosis, wherein said method comprises detecting S100-AG, S100-A7 and S100-A9, and a kit comprising a component for detecting said proteins, classified in class 435, subclass 7.1 and, for example, in class 530, subclass 388.1.

Group XXVII. Claims 1-7, insofar as the claims are drawn to a method for prognosis, wherein said method comprises detecting S100-A7, S100-A8, and S100-A0, and a kit comprising a component for detecting said proteins, classified in class 435, subclass 7.1 and, for example, in class 530, subclass 388.1.

Group XXVIII. Claims 1-7, insofar as the claims are drawn to a method for prognosis, wherein said method comprises detecting S100-AG, S100-A7, S100-A8, and S100-A9, and a kit comprising a component for detecting said proteins, classified in class 435, subclass 7.1 and, for example, in class 530, subclass 388.1.

Group XXIX. Claims 8-13, drawn to a method for diagnosis, wherein said method comprises detecting autoantibodies, and a kit comprising a component for detecting said autoantibodies, classified in class 436, subclass 7.1 and, for example, in class 530, subclass 350.

Group XXX. Claims 24-32, drawn to a method for immunizing a host, wherein said method comprises inoculating said host with S100-AG, classified in class 424, subclass 184.1.

Group XXXI. Claims 24-32, drawn to a method for immunizing a host, wherein said method comprises inoculating said host with S100-A7, classified in class 424, subclass 184.1.

Group XXXII. Claims 24-32, drawn to a method for immunizing a host, wherein said method comprises inoculating said host with S100-A8, classified in class 424, subclass 184.1.

Group XXXIII. Claims 24-32, drawn to a method for immunizing a host, wherein said method comprises inoculating said host with S100-A9, classified in class 424, subclass 184.1.

3. The inventions are distinct, each from the other because of the following reasons:

Inventions in groups I-XXIX are disclosed as biologically and chemically distinct, unrelated in structure and/or function, and/or made by and/or used in different methods and therefore, the claimed products are distinct.

Inventions in groups I-XXXIII are disclosed as materially different methods that differ at least in objectives, method steps, reagents and/or doses and/or schedules used, response variables, assays for end products and/or results, and criteria for success and therefore, the claimed methods are distinct.

4. Because these inventions are distinct for the reasons given above and also because the search required for any one group is not required for any other group and/or the inventions have acquired a separate status in the art as shown by their different classification or their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

5. The inventions of groups I-XXXIII are further subject to an election requirement.

Claim 1 is generic to a plurality of disclosed patentably distinct species wherein said cancer is selected from the group consisting of (a) lung cancer, (b) breast cancer, and (c) colon cancer, as set forth in claims 5, 6, and 7, respectively. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Claim 8 is generic to a plurality of disclosed patentably distinct species wherein said cancer is selected from the group consisting of (a) lung cancer, (b) breast cancer, and (c) colon cancer, as set forth in claims 11, 12, and 13, respectively. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Claims 24-26 are generic to a plurality of disclosed patentably distinct species wherein said cancer is selected from the group consisting of (a) lung cancer, (b) breast cancer, and (c) colon cancer, as set forth in claims 27, 28, and 29, respectively. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

6. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

7. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***C nclusion***

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (703) 305-3008. The examiner can normally be reached on Monday-Thursday, alternate Fridays, 8:00AM-5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C. Caputa, Ph.D. can be reached on (703) 308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Stephen L. Rawlings, Ph.D.
Examiner
Art Unit 1642

DONNA WORTMAN
PRIMARY EXAMINER

slr
September 11, 2002

# RESTRICTION ELECTION FACSIMILE TRANSMISSION

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